



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1204]

Draft Risk Profile on Pathogens and Filth in Spices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft risk profile entitled "FDA Draft Risk Profile: Pathogens and Filth in Spices" (draft risk profile). Our main objectives were to: Describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice; describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States; identify potential additional mitigation or control options designed to reduce the public health risk posed by the consumption of contaminated spices in the United States; and identify data gaps and research needs. The draft risk profile is intended to provide information for FDA risk managers to use in regulatory decision making related to the safety of spices in the U.S. food supply. The information may also be useful to stakeholders and interested parties such as spice producers and importers, spice and food manufacturers, retail food establishments, and consumers.

DATES: Submit either electronic or written comments on the draft risk profile by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the draft risk profile to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2927.

SUPPLEMENTARY INFORMATION:

I. Background

In response to recent outbreaks in the United States of human illness associated with consumption of certain spices, as well as other reports in the literature and within FDA suggesting that current pathogen control measures in spices may not adequately protect public health, we developed a draft risk profile on pathogens and filth in spices (Ref. 1). We initiated the draft risk profile in response to a large outbreak of Salmonella Rissen infections in 2008 to 2009 associated with the consumption of ground white pepper in the United States (id.). Subsequently, in 2009 to 2010, the United States had a larger outbreak of Salmonella Montevideo infections associated with consumption of products containing black and red pepper (id.). The objectives of the draft risk profile are to: (1) Describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice; (2) describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States; (3) identify potential additional mitigation and control options; and (4) identify data gaps and research needs.

Specific risk management questions that are addressed include:

- What is known about the frequency and levels of pathogen and/or filth contamination of spices throughout the food supply chain (e.g., on the farm, at primary processing/manufacturing, at intermediary processing (where spices are used as ingredients in multi-component products), at distribution (including importation), at retail sale/use, and at the consumer's home)?
- What is known about the differences in production and contamination of imported and domestic spices?
- What is known about the effectiveness and practicality of currently available and potential future mitigations and control options to prevent human illnesses associated with contaminated spices (e.g., practices and/or technologies to reduce or prevent contamination, surveillance, inspection, import strategies, or guidance)?
- What are the highest priority research needs related to prevention or reduction of contamination of spices with pathogens or filth?

The draft risk profile has undergone an independent external peer review, and our response to the peer review is available electronically on the FDA Web site (Ref. 2).

For the purpose of the draft risk profile, we consider "spice" to mean any dried aromatic vegetable substances in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed. We also consider dehydrated onion and garlic and other dehydrated vegetables used as seasoning to be spices.

The specific microbial hazards and filth in spices that we consider in the draft risk profile include those pathogen and filth adulterants detected in spices, implicated in outbreaks, reported as the reason for recalls, and reported in submissions to the Reportable Food Registry (RFR) (Ref. 3). The draft risk profile focuses on Salmonella, among the pathogens detected in spices, because it is the only spice-associated pathogen linked with human illness, food recalls, and RFR reports in the United States.

We invite comments that can help improve: (1) The data and information used; (2) the analytical analyses employed; and (3) the clarity and the transparency of the draft risk profile.

II. Comments

Interested persons may submit either electronic comments regarding the draft risk profile to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the draft risk profile at either (<http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367337.pdf>) or <http://www.regulations.gov>.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at <http://www.regulations.gov>.

(We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. U.S. Food and Drug Administration (2013). "FDA Draft Risk Profile: Pathogens and Filth in Spices." Accessible at <http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367337.pdf>.
2. U.S. Food and Drug Administration (2013). "FDA Draft Risk Profile: Pathogens and Filth in Spices: Peer Review Report: External Peer Review Comments and FDA Responses." Accessible at <http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367338.pdf>.
3. U.S. Food and Drug Administration (2013). Reportable Food Registry Annual Report. Accessible at <http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>.

Dated: October 28, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013-26119 Filed 10/30/2013 at 4:15 pm; Publication Date: 11/04/2013]